- 38 -

## **CLAIMS**

- 1. A method for treating a subject having non-fungal induced mucositis of the distal intestinal tract, comprising administering locally to the distal intestinal tract of the subject an anti-fungal azole compound in an amount effective to reduce or eliminate the non-fungal induced mucositis of the distal intestinal tract.
- 2. The method of claim 1, wherein the effective amount comprises in a single dosage about 2,000 mg to about 10,000 mg of the anti-fungal azole compound, at a frequency of administration from four times a day to once a month.
- 3. The method of claim 1, wherein the non-fungal induced mucositis of the distal intestinal tract is selected from the group consisting of: pouchitis, ulcerative colitis, Crohn's disease, allergic colitis, autoimmune colitis, autoimmune enteropathy, bacterial colitis, diversion colitis and lymphocytic colitis.
- 4. The method of claim 1, wherein the non-fungal induced mucositis of the distal intestinal tract is pouchitis.
- 5. The method of claim 1, wherein the mucositis of the distal intestinal tract is non-microbial induced.
- 6. The method of claims 1, wherein the dose is from 2,500 mg to 10,000 mg at a frequency of from twice a day to once every two weeks.
- 7. The method of claims 1-6, wherein the subject is a human.
- 8. The method of claim 7, wherein the anti-fungal azole compound is selected from the group consisting of: anti-fungal imidazole compounds, anti-fungal triazole compounds and anti-fungal nitroimidazole compounds.

- 39 -

- 9. The method of claim 8, wherein the anti-fungal azole compound is an antifungal imidazole compound.
- 10. The method of claim 9, wherein the anti-fungal imidazole compound is clotrimazole.
- 11. The method of claim 1, further comprising administering to the subject an amount of one or more non-azole compounds effective to treat the non-fungal induced mucositis of the distal intestinal tract.
- 12. The method of claim 11, wherein the non-azole compounds are selected from a list consisting of anti-inflammatory or anti-bacterial compounds.
- 13. An article of manufacture, comprising packaging material and an anti-fungal azole compound, wherein the article of manufacture further comprises a label or package insert indicating that the anti-fungal azole compound can be administered to a subject for treating a non-fungal induced mucositis of the distal intestinal tract.
- 14. The article of manufacture of claim 13, wherein the anti-fungal azole compound is present in a unit dosage of between about 2,000 mg and about 10,000 mg.
- 15. The article of manufacture of claim 13, wherein the label or package insert indicates that the anti-fungal compound can be administered to a human subject.
- 16. The article of manufacture of claim 15, wherein the label or package insert indicates that the anti-fungal compound can be administered for treating a non-microbial induced mucositis.

- 40 -

- 17. The article of manufacture of claim 15, wherein the anti-fungal azole compound is present in a unit dosage of about 2,500 mg to about 10,000 mg.
- 18. The article of manufacture of claim 15, wherein the anti-fungal azole compound is an anti-fungal imidazole compound.
- 19. The article of manufacture of claim 18, wherein the anti-fungal imidazole compound is clotrimazole.
- 20. The article of manufacture of claims 13-19, wherein the article of manufacture further comprises an enema component.
- 21. The article of manufacture of claim 20, wherein the enema component is either or both of an insertable enema tip or a container adapted for fluid connection with an insertable enema tip.
- 22. The article of manufacture of claim 21, wherein the container is a soft squeeze bottle.
- 23. The article of manufacture of either claim 21 or 20, further comprising of one or more of: a flow-control valve, a reflux-prevention valve, and a replaceable protective shield.
- 24. The article of manufacture of either claim 21 or 23, wherein the anti-fungal azole compound is in a liquid formulation contained in the container.
- 25. The article of manufacture of claim 24, wherein the anti-fungal azole compound is an anti-fungal imidazole compound.
- 26. The article of manufacture of claim 25, wherein the anti-fungal imidazole compound is clotrimazole.

- 41 -

- 27. The article of manufacture of claim 26, wherein the anti-fungal compound is in a formulation that is ready to use.
- 28. The article of manufacture of claim 26, wherein the article of manufacture is disposable.
- 29. The article of manufacture of claim 26, wherein the enema component is latex free.
- 30. The article of manufacture of claim 27, wherein the formulation is for rectal administration.
- 31. The article of manufacture of claim 20, further comprising one or more non-azole compounds that can be administered to a subject for treating a non-fungal induced mucositis of the distal intestinal tract.
- 32. The article of manufacture of claim 31, wherein the non-azole compounds are selected from a list consisting of anti-inflammatory or anti-bacterial compounds.
- 33. A pharmaceutical composition comprising an enteric coating containing an anti-fungal azole compound.
- 34. The pharmaceutical composition of claim 33, wherein the enteric coating releases the anti-fungal azole compound in the distal intestinal tract.
- 35. The pharmaceutical composition of claim 33, wherein the enteric coating releases the anti-fungal azole compound in a pH greater than 5.5.
- 36. The pharmaceutical composition of claim 33, wherein the enteric coating releases the anti-fungal azole compound in a pH greater than 7.

PCT/US2004/030813

WO 2005/027851

- 37. The pharmaceutical composition of claim 33, wherein the pharmaceutical composition is administered to a human for treating non-fungal induced mucositis.
- 38. The pharmaceutical composition of claim 33, wherein the pharmaceutical composition is administered to a human for treating non-microbial induced mucositis.
- 39. The pharmaceutical composition of claim 33, wherein the anti-fungal azole compound is present in an amount of about 2,000 mg to about 10,000 mg.
- 40. The pharmaceutical composition of claim 33, wherein the anti-fungal azole compound is present in an amount of about 2,500 mg to about 10,000 mg.
- 41. The pharmaceutical composition of claim 33, wherein the anti-fungal azole compound is an anti-fungal imidazole compound.
- 42. The pharmaceutical composition of claim 41, wherein the anti-fungal imidazole compound is clotrimazole.
- 43. The pharmaceutical composition of claim 33, further comprising one or more non-azole compounds for treating a non-fungal induced mucositis of the distal intestinal tract.
- 44. The pharmaceutical composition of claim 43, wherein the non-azole compounds are anti-inflammatory or anti-bacterial compounds.